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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,614	04/27/2006	Yvonne Paterson	P-7772-US	4019

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,614	PATERSON ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *10-19 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/26/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-30 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claim(s) 1-9, 20-27, drawn to methods of enhancing the immunogenicity of a bacterial vaccine vector n the reply filed on September 02, 2008 is acknowledged. The traversal is on the ground(s) that the instantly claimed invention does not lack unity of invention because the two references cited as describing the first appearing invention do not describe a method for enhancing immunogenicity.

2. This is not found persuasive because US Patent 5,628,994 at paragraph 15 states that the serial passaged strain" does not revert to toxigencity" and functioned as a "vaccine strain" and therefore served to enhance the immune response to the Vibrio cholera strain. Additionally, US Patent 5,861163 ,at Brief summary paragraph 2, found the isolated Fisher-Devlin immunotype to be a vaccine strain that is attenuated but immunogenic, the vaccine strain inducing an enhanced immune response to the bacterial strain. The first appearing invention (claim 1) does not make a contribution over the prior art, therefore the special technical feature claimed does not define a special technical feature that makes a contribution over the prior art resulting in a lack of unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims of Group II, claim(s) 10-19, 28-30, drawn to a bacterial vaccine vector and a kit that comprises a bacterial vaccine vector, that is lyophilized or in a pharmaceutically acceptable carrier are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 2, 2008.

Information Disclosure Statement

4. The information disclosure statement filed February 6, 2008 has been considered.

Specification

5. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-3, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mora et al US

Patent 3,328,252.

(Instant claims 1-3, 9) Mora et al teach the claimed special technical feature directed to a method that comprises the steps of :

administering a bacterial vaccine vector which expresses an antigen (Pasteurella), the administering being parenteral (injection, see col. 3, lines 59-66),

passaging the bacterial vaccine vector through an animal (see col. 4, "chickens", lines 44-50),

harvesting the bacterial vaccine vector from the animal ("maintained or oftener passage through disease-free chickens two to four weeks of age" , "isolations being made from the liver of chickens after it died from infection),

repeating the method until a maximum bacterial load in an organ is reached (maximum load in the liver lead to death of the chickens; this process was repeated with "single cell colony isolations being made from the liver of the chickens", col. 4, lines 44-50).

(Instant claims 10-12,18-19) Mora et al teach the claimed special technical feature of a bacterial vaccine vector that expresses an antigen, that is formulated into a parenteral composition for administration with a pharmaceutically acceptable carrier ("an aqueous or an emulsified oil medium, see col. 3, lines 62-63). The bacterial strain was passaged in mice in vivo to obtain a maximum load (see method above for support for the functional methods steps recited), and would therefore induce the maximum immune response. Mora et al anticipate the instantly claimed invention.

8. Claims 1,3,7,9, are rejected under 35 U.S.C. 102(b) as being anticipated by Mankoski et al (1999).

(Instant claims 1,3,7,and 9) Mankoski et al disclose the instantly claimed method directed to a method that comprises the steps of :

administering a bacterial vaccine vector which expresses an antigen (Helicobacter pylori) , the administering being orally (see page 395, col. 2, paragraph 2),

passaging the bacterial vaccine vector through the animal (see abstract" in-vivo

passage"),

harvesting the bacterial vaccine vector from the animal ("piglets were killed 28 days after inoculation", page 395, col. 2, paragraph 2),

repeating the method (see abstract) until a maximum bacterial load in an organ is reached ("results in a greater colonization efficiency in subsequent infections", see abstract first sentence").

Mankoski et al anticipates the instantly claimed invention.

9. Claims 1-9, 20-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Frankel et al (US Patent 6.099,848).

10. Frankel et al disclose a method, the method comprising the steps for enhancing the immunogenicity of a bacterial vaccine vector, the method comprising:

Instant claims 1 and 20:

a) administering (see col. 5, lines 18-21; col. 10, line 39 "oral", "parenteral") to an animal (mammal, col. 5, line 19; mice see col. 14, line 14) the bacterial vaccine vector (see col. 2, lines 39-40); col. 2, lines 49-52;)

b) passaging the bacterial vaccine vector through the animal ("enhanced CTL response", col. 10, lines 65-67;

c) harvesting (splenocytes obtained from a given animal", col. 16, line 13; "spleens were removed from the mice col. 16, line 33") the bacterial vaccine vector from the animal, and;

d) repeating step a), step b), and step c) (two splenocyte samples taken from the same animal, col. 16, lines 12-17, see col. 19, lines 14-38 and col. 20, lines 1-3 (confirmation that attenuated bacteria were able to induce protection; col. 16, lines

9-19 "the mice were boosted with a second inoculation containing the same number of microorganisms") until a maximum bacterial load ("100-fold fewer bacteria were detected in the spleens of mutant infected mice compared with wild type animals", col. 20, lines 1-2) in an organ (spleen) is reached, thereby enhancing (see col. 10, lines 51-54 "induce an enhanced CTL response") the immunogenicity of the bacterial vaccine vector (the antigen being a heterologous antigen (see col. 2, lines 48-52; HIV-1 antigen (see col. 2, line 53), viral, bacterial, fungal, parasite or tumor antigens (see col. 7, lines 15-16, 20).

Instant claims 2 and 21. The method of claim 1 wherein the organ is a spleen (see col. 20, line 2 "spleens").

Instant claim 3-4, 20,22 . The method of claim 1 wherein the bacterial vaccine vector expresses an antigen (see col. 2, lines 65-67).

Instant claims 5, 23: tumor antigen(see col. 7, line 20).

Instant 6 and 24: Listeria vaccine vector (see col. 2, lines 39-40).

Instant claims 7, 25: the animal is a mammal (see col. 4, line 65 "mammals")

Instant claims 8 and 26: the mammal is a mouse (see col. 19, line 15 "mice", col. 20, line 19 "mice")

Instant claims 9 and 27 :"Oral" (see col. 10, line 39 "oral route"), parenteral (see col. 10, line 39; col. 20, lines 16 "intraperitoneally")

Frank et al anticipate the instantly claimed invention as now claimed.

11. Claims 1-9 , 20-27 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 01/25399 A2 (reference of record, sited on US PTO 1449).

WO 01/25399 disclose the instantly claimed invention directed to a method that comprises the steps of :

administering a bacterial vaccine (Salmonella, Listeria, Shigella, see claim 62) vector

which expresses a heterologous (see page 37, line 17) immunogenic antigen (see page 37, line 12), the administering (see page 49, lines 32-36; page 50, paragraph 1, lines 6-8) being either oral (page 49, paragraphs 2 and 4; page 13, lines 34-36) or parenteral ("injected, page 56, Example 6, section 6.1),

passaging the bacterial vaccine vector through the animal (the vector passes to an organ, specifically the liver (see Table 4, page 56) or tumor (see claim 62 "renal" , "thyroid", "pancreatic", "stomach", "colon", "prostate", etc),

harvesting the bacterial vaccine vector from the animal (Figure 4, and page 12, lines 7-9; "biopsy of tumor cells is used in the selection assay for isolating a vector which is super-infective and tumor specific for the tumor of the subject", see page 14, lines 26-17; "the amount of vector targeted to the tumor", page 17, line 34; page 33, paragraph 1, "the number of infecting bacteria found at the target tumor or tumor cell as compared to the non-cancerous counterparts becomes larger and larger as the dilution of the bacterial culture is increased, page 33, paragraph 1),

repeating the method until a maximum bacterial load in an organ is reached (10^9 for tumor and 10^6 for liver, see Example 6, pages 56-57 was determined to maximum load). (Instant claims 10-19 and 28-30) WO 01/25399 teaches the claimed special technical feature of a bacterial vaccine vector that expresses a heterologous (see page 39, paragraph 1) tumor antigen (see page 37, paragraph 1), that is formulated into an oral or parenteral composition for administration (see 49, paragraphs 2 and 4), and kits (see all claims, page 54, section 5.11 and page 51, section 5.9) that comprise the vaccine vector bacterial strains that are lyophilized (see page 52, paragraph 1, line 1), together with instructions (see page 54, section 5.11), and the carrier being a defined to include a carrier system (see page 50, paragraphs 2-3, a type of applicator). WO 01/25399 anticipates the instantly claimed invention.

12. Claims 1-3, 7-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Kleanthous et al (2001).

(Instant claims 1-3, 7-9) Kleanthous et al (2001) disclose the instantly claimed invention directed to a method, the method comprising the steps of :

administering a bacterial vaccine vector which expresses an antigen (Helicobacter pylori

antigen) , the administering (see page 4884, section 2.2) being oral (intragastric "i.g', section 2.2),

passaging the bacterial vaccine vector through the animal ("mice were euthanized and infection with H. pylori was assessed", page 4884, section 2.2, and section 2.3, tissue harvested from the stomach for harvesting bacteria),

harvesting the bacterial vaccine vector from the animal ("Upon re-isolation"section 2.2),

repeating the method (see Table 1, page 4886) until a maximum bacterial load in an organ is reached ("in vivo adaptation process was repeated until no further increase was observed in the level of gastric colonization", section 2.2" and abstract "sterilizing immunity"). (Instant claims 10,12,16-19) Kleanthous et al teach the claimed special technical feature of a bacterial vaccine vector that expresses an antigen (urease activity, see Table 1, page 4886), that is formulated into an oral composition for administration (see page 4885, section 2.4), with a pharmaceutically acceptable carrier, phosphate buffered saline (see section 2.4, page 4885). The bacterial strain was passaged in mice in vivo to obtain a highly infectious strain (see abstract), which produced a bacterial load in gastric tissue higher than the parent strain (see abstract, Table 1, page 4886, 4 in vivo passages). The reference anticipates the instantly claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/

Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645